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| APPLICATION NO.                               | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/912,049                                    | 07/24/2001  | Thomas G. Rehberger  | 362.003             | 4550             |
| 23598   | 7590        | 05/03/2004           |                     |                  |
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| SUITE 1030                                    |             |                      |                     |                  |
| MILWAUKEE, WI 53202                           |             |                      |                     |                  |
|   |             |                      | EXAMINER            |                  |
|   |             |                      | MARX, IRENE         |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1651                |                  |

DATE MAILED: 05/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |   |  |
|------------------------------|--------------------------------------|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/912,049 | <b>Applicant(s)</b><br>REHBERGER ET AL. |  |
|                              | <b>Examiner</b><br>Irene Marx        | <b>Art Unit</b><br>1651                 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 February 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3-7, 9, 42-50, 52-54, 56, 58-64, 67 and 71-81 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-7, 9, 42-50, 52-54, 56, 58-64, 67, 71-81 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/23/04 has been entered.

Claims 3-7, 9, 42-50, 52-54, 56, 58-64, 67, 71-81 are being considered on the merits

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-7, 9, 42-50, 52-54, 56, 58-64, 67, 71-81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in the recitation “of an effective amount for colonization of the rumen”, since the amount for this purpose would depend not only on the microorganism selected, but also on the timing of feedings and on the age and type of ruminant selected. Applicants have only indicated such amounts with respect to cows for a specific strain of *Propionibacterium*.

Claims 3 and 50 are confusing in the use of parenthesis. It is recommended that the parenthesis be deleted.

Claim 4 and 49 are vague and indefinite in the recitation of Figures 1-2, since these figures are illegible and cannot properly be interpreted. Also there is a discrepancy between the claim notation and the notation in Table 3 regarding “I” v. “1”. Correction is required.

Claims 4 and 50 are substantial duplicates.

Claim 2 fails to find proper antecedent basis in claim 1 for “the strain”.

Claims 42-48 fail to further limit claim 3; claims 58-60, 61-64 fail to further limit claim 49; claims 75-81 fail to further limit claim 71, since the testing steps are unrelated to the feeding step.

Claims 46, 47, 48, 62-64 and 81 are vague, indefinite and confusing in that there is no clear feeding of a suitable microorganism to achieve the touted results. The claims merely require "feeding the ruminant"... In addition there is no indication of how much of the microorganism is provided and how often. Also the claims are internally inconsistent in that the ruminant output appears to be measured before lactation. From the specification, it is apparent that two groups of ruminants are involved, an experimental group and a control. It is recommended that "ruminants" be used where appropriate and that the claims be amended to conform with the experiments performed and reported. See also the new matter rejections.

Claims 6, 7, 53, 54 and 72 fail to find proper antecedent basis in claims they depend on for "delivered". Claims 73 is confusing in that it fails to find clear antecedent basis for "fed" in claim 72.

Claim 78 is vague and indefinite in that it cannot be readily ascertained how long the bovine is to be fed, since the amount fed and the period of feeding is not defined in claim 71.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-7, 9, 42-50, 52-54, 56, 58-64, 67, 70 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Insertion of the limitation "microorganisms of the genus *Propionibacterium* which has the following characteristics: (1) producing at least 0.9 % (vol/vol) propionate in sodium lactate broth, and (2) producing at least 0.2% (vol/vol) propionate in rumen fluid (in vitro and/or has a group I profile produced by Xba 1 digests of genomic DNA as shown in Figures 1-2 and Table 3" with respect to results of testing reported in claims 42-48 and 58-64 does not have support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show

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possession of the concept of the use of “microorganisms of the genus *Propionibacterium* which has the following characteristics: ( 1) producing at least 0.9 % (vol/vol) propionate in sodium lactate broth, and (2) producing at least 0.2% (vol/vol) propionate in rumen fluid (in vitro and/or has a group I profile produced by Xba 1 digests of genomic DNA as shown in Figures 1-2 and Table 3”. There is no clear nexus regarding the possession of the property of producing at least 0.9 % (vol/vol) propionate in sodium lactate broth, and (2) producing at least 0.2% (vol/vol) propionate in rumen fluid (in vitro) and the property of having a group I profile produced by Xba 1 digests of genomic DNA as shown in Figures 1-2 and Table 3”. The only strain shown to have both is strain P169. This is not sufficient support for the new genus. This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Thus, the insertion of “microorganisms of the genus *Propionibacterium* which has the following characteristics: ( 1) producing at least 0.9 % (vol/vol) propionate in sodium lactate broth, and (2) producing at least 0.2% (vol/vol) propionate in rumen fluid (in vitro and/or has a group I profile produced by Xba 1 digests of genomic DNA as shown in Figures 1-2 and Table 3” is considered to be the insertion of new matter for the above reasons.

In addition, no basis or support is found in the present specification for statistically significant differences based on “microorganisms of the genus *Propionibacterium* which has the following characteristics: ( 1) producing at least 0.9 % (vol/vol) propionate in sodium lactate broth, and (2) producing at least 0.2% (vol/vol) propionate in rumen fluid (in vitro and/or has a group I profile produced by Xba 1 digests of genomic DNA as shown in Figures 1-2 and Table 3”. Extrapolation from strain P169 to the above genus is improper and raises material issues of new matter.

### ***Rejections under 35 U.S.C § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 71-81 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel *Propionibacterium* P169 and P170. It is not clear if the written description is sufficiently repeatable to avoid the need for a deposit. Further it is unclear if the starting materials were readily available to the public at the time of invention.

It appears that a deposit was made in this application as filed as noted on page 10 of the specification. However, it is not clear if the deposit meets all of the criteria set forth in 37 CFR 1.801-1.809. Applicant or applicant's representative may provide assurance of compliance with the requirements of 35 U.S.C § 112, first paragraph, in the following manner.

#### SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

1. Identifies declarant.
2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.
3. States that the deposited material has been accorded a specific (recited) accession number.
4. States that all restriction on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.
5. States that the material has been deposited under conditions that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C § 122.
6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit for the enforceable life of the patent, whichever period is longer.
7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true,

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and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

Also, the specification is incomplete in that the deposit accession numbers are missing. Correction is required.

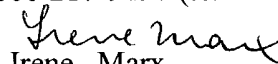
The rejection under 35 U.S.C 102 over Rehberger *et al.* and Ott *et al.* are withdrawn in view of the Rehberger declaration presented.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Irene Marx  
Primary Examiner  
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